

NON-CONFIDENTIAL

04-1323

**In The
United States Court of Appeals
For the Federal Circuit**

ARTHROCARE CORPORATION,

*Plaintiff-Counterclaim Defendant-Appellee,
and*

ETHICON, INC.,

Counterclaim Defendant-Appellee.

v.

SMITH & NEPHEW, INC.,

Defendant-Counterclaim Plaintiff-Appellant.

**APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE
DISTRICT OF DELAWARE IN 01-504-SLR,
CHIEF JUDGE SUE L. ROBINSON**

**SMITH & NEPHEW, INC.'S EMERGENCY MOTION TO STAY
INJUNCTION UNDER FEDERAL CIRCUIT RULE 8**

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I. INTRODUCTION

This is an emergency motion under Fed. Cir. Rule 8 by Defendant-Counterclaim Plaintiff-Appellant Smith & Nephew, Inc. ("Smith & Nephew") to stay entry of an injunction by the district court. A motion to stay filed by Smith & Nephew was denied by the district court on April 27, 2004 (Ex. 10 and Ex. 11 at 15).¹ A motion for entry of permanent injunction was granted by the district court on March 10, 2004 (Ex. 4 and Ex. 5 at 89-90), and a motion to reconsider that decision was denied by the district court on April 27, 2004 (Ex. 10 and Ex. 11 at 7). It is believed that entry of a permanent injunction by the district court is imminent. All other parties, *i.e.*, Plaintiff-Counterclaim Defendant-Appellee ArthroCare Corp. ("ArthroCare") and Counterclaim Defendant-Appellee Ethicon, Inc. ("Ethicon") have been notified in advance of this emergency motion.

Confidential information removed from this motion include terms found in the ArthroCare/Ethicon Settlement Agreement and Smith & Nephew financial information.

II. SUMMARY OF GROUNDS FOR THIS MOTION

1. The district court dismissed Smith & Nephew's antitrust counterclaim based on clear errors of procedure and law, and denial of due process. First, the district court denied due process when it ordered Smith & Nephew not to file an opposition to ArthroCare's motion to dismiss and then granted that motion as unopposed. The district court specifically ordered a stay of all proceedings in connection with the counterclaim — including briefing on the motion to dismiss

¹ Pursuant to FRAP 8(a)(2)(A)(ii), the reasons given by the district court for denying Smith & Nephew's motion to stay are discussed herein.

after it was filed but before Smith & Nephew's response was due. The court then erroneously presumed Smith & Nephew did not oppose it. Second, the Court erroneously concluded that the antitrust counterclaim was predicated solely upon sham litigation, ignoring the patent misuse grounds set forth in the counterclaim. Smith & Nephew's erroneously dismissed counterclaim renders the ArthroCare patents-in-suit unenforceable. Accordingly, to avoid manifest injustice, the injunction should be stayed pending appeal.

2. There are substantial close issues as to the validity of the ArthroCare patents-in-suit. All three patents are in the process of being reexamined in the U.S. Patent and Trademark Office ("PTO"), which found a "substantial new question of patentability" as to all three patents. The reexaminations have also found that the key teachings of the prior art references were not recognized during the original prosecution. As such, there is a high likelihood that the claims of the patents will be rejected and amended during the reexamination proceedings.

3. There are substantial legal issues that Smith & Nephew will raise on appeal that will require reversal or remand. These include claim construction issues, as well as the validity of a Certificate of Correction which the district court improperly submitted to the jury, which appears to be a matter of first impression for this Court. All of these combine to produce a substantial likelihood of success on the merits. A stay of the injunction will permit this Court to resolve these issues and avoid an injunction based on flawed patents and procedure.

4. The balance of the equities and the public interest in this case favor a stay. Smith & Nephew will suffer immediate irreparable injury if the injunction is

not stayed. On the other hand, ArthroCare has previously licensed these patents to the rest of the market, demonstrating that money damages alone will provide relief. The public interest also favors a stay to avoid needlessly depriving surgeons of an important therapeutic tool and to avoid supporting ArthroCare's attempt to collude with others to restrain competition in the market for RF surgical probes.

III. ARGUMENT

A. A STAY IS APPROPRIATE UNTIL ENFORCEABILITY OF ARTHROCARE'S PATENTS IS DETERMINED

No permanent injunction should be enforced until it has been determined that Smith & Nephew is liable for infringement of a valid *and enforceable* patent. The district court made two clear errors in granting ArthroCare's Motion to Dismiss Smith & Nephew's Antitrust Counterclaim. Until that counterclaim is adjudicated on the merits, the enforceability of ArthroCare's patents is in serious doubt. Indeed, until Smith & Nephew's enforceability defense is considered, it cannot be said that ArthroCare is entitled to permanent relief *of any kind*. Essentially what the district court has done is to issue a preliminary injunction before all of Smith & Nephew's defenses have been resolved, without making the findings required to support preliminary relief.

Smith & Nephew's antitrust counterclaim is substantial and strikes directly at the enforceability of the patents in suit. The facts which must be presumed true in this motion to dismiss context are that ArthroCare colluded with Ethicon — who together control over 75% of the relevant market — to monopolize that market. ArthroCare sued Ethicon in 1988 on some of the same patent claims at issue here.

When the district court in that case ruled that the ArthroCare claims were likely invalid as part of a preliminary injunction opinion, ArthroCare and Ethicon colluded to exchange a license to the patent rights for an agreement [

]. These are serious and far-reaching claims that have a direct nexus to the patents-in-suit and should lead to a patent misuse unenforceability finding. *See, e.g., Burlington Indus., Inc. v. Milliken & Co.*, 690 F.2d 380, 388 (4th Cir. 1982) (confirming that patent misuse arises where a conspiratorial settlement of an earlier patent infringement suit “served as a vehicle for collusive restraint of trade.”); *Ansul Company v. Uniroyal, Inc.*, 448 F.2d 872, 879, 882 (2d Cir. 1971).

The antitrust portion of the case must be resolved to determine whether the patents are enforceable. The district court explicitly linked grant of the injunction to dismissal of the antitrust counterclaim: “The court granted ArthroCare’s motion

² Notably, the district court prevented Smith & Nephew from introducing the prior district court opinion which made specific findings about the content of the prior art and its correspondence to claims at issue here.

³ [

]

to dismiss ... *For this reason*, the court concludes it is not premature to issue a permanent injunction at this time." (Ex. 5 at 90, n.29) (emphasis added).

1. The District Court Erred in Dismissing Smith & Nephew's Antitrust Counterclaim Because It Stayed Briefing on ArthroCare's Motion to Dismiss

In granting ArthroCare's motion to dismiss, the district court cited that Smith & Nephew did not file an opposition to ArthroCare's motion, and presumed the motion unopposed. (Ex. 8 at 3, n.1). The district court's presumption was not correct. Smith & Nephew did not file an opposition only because the court *ordered* a stay of all proceedings on the antitrust issues on June 9, 2003, after ArthroCare filed its motion, but before Smith & Nephew was to respond:

Yes, I think basically the proper wording, which I'm not going to put in an order, it's part of the transcript, is that the antitrust damages and willfulness issues are stayed until further Order of the Court.

(Ex. 17 at 12, lines 21-24).

There is no need to do any further briefing and that will be stayed until we address all of the stayed issues in September or by my order.

(*Id.* at 14, lines 21-23).

Mr. Hebert [Smith & Nephew's counsel]: There is a pending motion to dismiss the antitrust claim. I would understand that is stayed as well.

THE COURT: Yes.

(*Id.* at 15, lines 2-5) (emphasis added).

So everything is stayed and we'll deal with the antitrust issues later. That's what I said and that's what I mean. So the pending motion on antitrust is stayed and everything having to do with the antitrust counterclaims, discovery, substantive motions, et cetera, is stayed pending further order of the Court.

(*Id.* at 15, line 21 to page 16, line 1).

The district court never lifted the stay, and never permitted Smith & Nephew to file an opposition to ArthroCare's motion to dismiss.⁴ Instead, the district court granted the motion as unopposed. Fundamental fairness and due process requires that Smith & Nephew be given an opportunity to be heard on the merits in connection with the Motion to Dismiss. *Dougherty v. Harper's Magazine Co.*, 537 F.2d 758, 761 (3d Cir. 1976) (internal citations omitted):

Rule 12(d), FRCP requires that a Rule 12(b)(6) motion for dismissal ... may be disposed of only after a hearing, which affords an opportunity to present legal arguments either orally, in writing, or both at the District Court's discretion. The right to hearing is "the essence of our judicial system, and the judge's feeling that the case is probably frivolous does not justify bypassing that right." ... In *Jordan v. County of Montgomery, Pennsylvania*, ... we held that an order dismissing a complaint under Rule 12(b)(6), entered without affording the plaintiff an opportunity to be heard, must be reversed. We note that in *Council of Federated Organizations v. Mize*, 339 F.2d 898 (5th Cir. 1964), the Court characterized as a denial of due process the entry of an order dismissing the complaint for failure to state a claim without giving the plaintiff an opportunity to be heard.

Similarly, the Supreme Court held:

⁴ In fact, the district court denied Smith & Nephew's *unopposed* motion to lift the stay as untimely. (Ex. 9). There, the district court held that it only stayed discovery and trial of the antitrust counterclaim in a November 27, 2002 order and that "Smith & Nephew's reliance on one statement from a June 2003 teleconference is misplaced." (Ex. 11 at 6, n.3). However, that same footnote reflects that the June 9, 2003 telephone conference, held long after the November 27, 2002 order, was after ArthroCare had filed its motion to dismiss (which the district court treated as timely) but before Smith & Nephew's opposition was due. (*Id.*). The foregoing excerpts from that hearing show that Smith & Nephew justifiably relied on the repeated explicit statements from the district court that all further briefing on ArthroCare's motion to dismiss was stayed pending further order by the court. Indeed, in an e-mail to the court dated April 23, 2004, Counterclaim Defendant Ethicon represented that it had the very same understanding. (Ex. 18).

Under Rule 12(b)(6), a plaintiff with an arguable claim is ordinarily accorded notice of a pending motion to dismiss for failure to state a claim and an opportunity to amend the complaint before the motion is ruled upon. These procedures alert him to the legal theory underlying the defendant's challenge, and enable him meaningfully to respond by opposing the motion to dismiss on legal grounds or by clarifying his factual allegations so as to conform with the requirements of a valid legal cause of action.

Neitzke v. Williams, 490 U.S. 319, 329-30 (1989). Even assuming, *aguendo*, that Smith & Nephew's antitrust counterclaim was somehow flawed, the district court abused its discretion, and violated due process, in dismissing that claim without permitting Smith & Nephew to respond to the dismissal motion. Dismissal of Smith & Nephew's antitrust counterclaim was clearly improper, and the injunction should be stayed until that counterclaim is resolved.

2. The District Court Erred in Dismissing Smith & Nephew's Antitrust Counterclaim as Based on Sham Litigation

The district court's procedural error also resulted in a mistake of law – having only the ArthroCare side of the issue, the district court erroneously treated Smith & Nephew's antitrust counterclaim as based solely on sham litigation. (See Ex. 11 at 5-7). ArthroCare's Motion to Dismiss repeatedly and systematically mischaracterized the counterclaim as one based on a "sham lawsuit," which then became the conclusion of the district court. However, Smith & Nephew's antitrust claim is "based upon the illegal conspiracy in restraint of trade between ArthroCare and Ethicon, as evidenced by the ArthroCare/Ethicon agreement" and not on a sham lawsuit by ArthroCare. (Ex. 19 at 11, 13). Although the counterclaim included allegations that the conspirators knew the lawsuit was baseless (Ex. 20 at ¶¶ 30, 31 and 36), its primary thrust remains that [

], violates Section 1 of the Sherman Act. (*Id.* at ¶¶ 33, 34, 35, 37):⁵

33. In the Settlement Agreement between ArthroCare and Ethicon ("the Settlement Agreement"), ArthroCare agreed, *inter alia*, [

].

34. Upon information and belief, ArthroCare and Ethicon settled the first ArthroCare litigation to prevent or restrain other competitors from entering the market...

35. Upon information and belief, ArthroCare and Ethicon have at least a 75% share of the market in the United States for arthroscopic RF surgical devices, which is the relevant market for this antitrust claim. This combined market share of at least 75% gives ArthroCare and Ethicon substantial market power and the ability to restrain competition in the relevant market.

37. By conduct alleged herein, ArthroCare and Ethicon have entered into a combination or conspiracy in unreasonable restraint of trade in the relevant market in violation of Section 1 of the Sherman Act, 15 U.S.C. §1...

The district court was required to accept these allegations and all reasonable inferences as true, *Hospital Building Co. v. Trustees of Rex Hospital*, 425 U.S. 738, 740 (1976); *Fuentes v. South Hills Cardiology*, 946 F.2d 196, 197, 201 (3d Cir. 1991), and was prohibited from dismissing the counterclaim unless it was "beyond doubt that [Smith & Nephew] can prove no set of facts in support of [its] claim..." *Conley v. Gibson*, 355 U.S. 41, 45-46 (1957)). However, instead, the court ignored

⁵ These allegations sufficiently set forth the three elements necessary for an action under Section 1 of the Sherman Act. *Fuentes*, 946 F.2d at 198.

all of the allegations of conspiracy and collusion set forth in the counterclaim. Contrary to the district court's cursory analysis, Smith & Nephew's pleading sets forth a claim for a *per se* violation of the Sherman Act based on ArthroCare's collusion with Ethicon, its only other significant competitor in this market apart from Smith & Nephew. The antitrust counterclaim alleges collusion between ArthroCare and Ethicon to use the very patents-in-suit "as an anticompetitive weapon to interfere directly with business relationships of a competitor." (Ex. 20, ¶ 36).

A patent licensing agreement reached between two or more parties may constitute an unreasonable restraint on trade in violation of the Sherman Act, where the agreement is part of a plan to exclude or restrain other competitors. *See, e.g., U.S. v. Singer Mfg. Co.*, 374 U.S. 174, 192-94 (1963); *U.S. v. Krasnov*, 143 F.Supp. 184, 198-99 (E.D. Pa. 1956), *aff'd per curiam*, 355 U.S. 5 (1957); *U.S. v. New Wrinkle, Inc.*, 342 U.S. 371, 378-79 (1952) (finding that valid patents provided no protection to the prohibitions of the Sherman Act where licenses were used as part of a scheme to restrain trade).

While a patentee's unilateral decision not to license its patent may be acceptable, concerted action between the patentee and licensee violates Section 1 of the Sherman Act when they collectively conspire to exclude or restrict others from the market. *See Singer Mfg.*, 374 U.S. at 197 (noting that Sherman Act imposes strict limitations on concerted activities in which patent owners may be

lawfully engaged); *U.S. v. U.S. Gypsum*, 333 U.S. 364, 401 (1948).⁶ An almost identical fact situation — [

] against a strikingly similar set of background facts — was found to violate the antitrust laws in *Duplan Corp. v. Deering Milliken, Inc.*, 444 F.Supp. 648, 675-87 (D.S.C. 1977).

Furthermore, where two or more parties to a patent licensing agreement conspire to exclude another competitor from the market, the situation is tantamount to a group boycott arrangement. *U.S. v. National Lead Co.*, 63 F.Supp. 513, 524 (S.D.N.Y. 1945) (“[W]here there is a refusal to license...which is the product of agreement or conspiracy...the law is offended to the same extent as the law is violated when several combine and agree not to do business with a particular customer...”), *aff’d*, 332 U.S. 319 (1947).⁷ Conventional application of antitrust law has long held that combined refusals to deal or “group boycotts” involving firms with market power may be so likely to restrict competition that they amount to violations of the Sherman Act. *See, e.g., Northwest Wholesale Stationers, Inc. v. Pacific Stationery and Printing Co.*, 472 U.S. 284, 290 (1985); *Klor’s, Inc. v.*

⁶ In *Singer Mfg.*, as in this case, the cross-licensing arrangement was formed in order to exclude competitors. 374 U.S. at 194-95. It was this concerted action to restrain trade, the Court found, that violated the Sherman Act. *Id.* at 194-95.

⁷ In *National Lead*, the Court found that the agreement reached between producers of titanium products, involving cross-licensing of present and future patents and stipulations for refusal to license except upon certain conditions — [

] implicated the antitrust laws in the same manner as do group boycott scenarios. 63 F.Supp. at 524. “Whether the form of association they created be a cartel, an international cartel, a patent pool, or a ‘technical or commercial cooperation,’ is of little significance. It is a combination and conspiracy in restraint of trade; and the restraint is unreasonable. As such it is outlawed by Section 1 of the Sherman Act.” *Id.* at 523.

Broadway-Hale Stores, Inc., 359 U.S. 207, 212 (1959); *Fashion Originators Guild v. Federal Trade Commission*, 312 U.S. 457, 466-68 (1941); *Gill v. Delaware Park, LLC*, 294 F.Supp.2d 638, 644 (D. Del. 2003).

Smith & Nephew has presented a compelling case that the patents in suit are unenforceable due to an antitrust violation, a direct challenge to ArthroCare's entitlement to equitable relief. Smith & Nephew was prevented from responding to ArthroCare's motion to dismiss, and the one-sided record presented by ArthroCare and accepted wholesale by the district court has produced an erroneous result. At the very least, the injunction in this case should be stayed to permit Smith & Nephew to expose ArthroCare's anticompetitive acts before this Court.

B. A STAY IS NECESSARY TO AVOID INJUSTICE

To determine whether a stay is appropriate, this Court considers: (1) Smith & Nephew's likelihood of success on appeal; (2) Smith & Nephew's irreparable harm absent a stay; (3) whether any other interested party would suffer substantial injury from the grant of a stay; and (4) the public interest. *Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 897 F.2d 511, 512 (Fed. Cir. 1990).

1. Smith & Nephew Has A Reasonable Likelihood Of Success on Appeal

Smith & Nephew need not prove that it will necessarily win on appeal, only that its chance of success is reasonable. See, e.g., *Intel Corp. v. ULSI System Technology, Inc.*, 995 F.2d 1566, 1568, n5 (Fed. Cir. 1993).

a. **The Validity of ArthroCare's Patents Is In Doubt**

The PTO has granted Smith & Nephew's requests for reexamination for each of the ArthroCare patents finding a "substantial new question of patentability" with respect to each patent, placing the validity of these patents in serious jeopardy. (Exs. 21-23). The district court wrestled with the different standards applied by the PTO and in litigation, and erroneously held that the pending reexaminations have no impact on the likelihood of success prong of the *Standard Havens* test. (Ex. 11 at 8-9). However, the facts in *Standard Havens* are remarkably close to the facts here. The *Standard Havens* reexamination, like the present PTO proceedings, was based on the same prior art that had been considered at trial, and which the jury found did not invalidate the patent.⁸ In both this and the *Standard Havens* reexaminations, the PTO went beyond simply concluding that there was a substantial new question of patentability and made *findings* regarding both the teaching in the prior art and that such teaching had apparently been overlooked during the prior examination. *Id.* at 514. For example, in ordering the reexamination of the U.S. Patent No. 6,224,592 (Ex. 15) in this case, the reexamination examiner found (Ex. 23 at 2-3, 4):

Roos '198 discloses an electrically conducting fluid in claim 1. The teaching of an electrically conducting fluid by Roos '198 was not considered in the prosecution of the application, which became the Eggers et al. patent. ... Accordingly Roos '198 raises a substantial new question of patentability ... which question has not been decided in a previous examination of the Eggers et al. patent.

* * *

⁸ Compare *Standard Havens*, 897 F.2d at 512 with *Standard Havens Prods., Inc. v. Gencor Indus., Inc.*, 1989 U.S. Dist. Lexis 10333, *7 (W.D. Mo. 1989).

In addition, the examiner finds that the Roos '198 prior art, which was already considered by the examiner in the prosecution of the Eggers et al. patent, is presented in a new light with respect to the washing fluid being conductive.... This teaching was not pointed out in the Eggers et al. patent, and apparently not recognized by the examiner.

In *Standard Havens*, this Court concluded that the PTO's findings in the reexamination determination raised a "substantial question" of validity, which was sufficient to meet the "likelihood of success" prong of the test for a stay pending appeal. *Id.* at 514-15. In view of the PTO's remarkably similar findings with respect to the reexamination of ArthroCare's patents in this case, this Court should similarly find that the likelihood of success prong is met here as well.

Moreover, statistically speaking, there is a nearly 70% likelihood that the PTO will at the very least alter the claims (Ex. 24), meaning that any injunction will stand unsupported. Smith & Nephew has more than a reasonable likelihood of success during appeal and reexamination, and this factor strongly favors a stay.

b. There Are Many Close Claim Construction and Other Legal Issues on Appeal

Substantial legal issues, including substantial questions concerning claim interpretation exist in this case, each of which would be dispositive of infringement of the particular patent involved. In denying a stay, the district court did not weigh Smith & Nephew's arguments regarding claim construction errors, but instead simply held that the "possibility of appellate *de novo* review of its claim construction does not" warrant a stay. (Ex. 11 at 10). However, the closeness of the claim construction in this case cannot be ignored. For example, the parties

hotly disputed the interpretation of the term "connector."⁹ Claim 45 of U.S. Patent No. 5,697,536 ("the '536 patent", Ex. 13) requires "a connector near the proximal end of the shaft electrically coupling the electrode terminal to the electrosurgical power supply." As urged by Smith & Nephew, the proper interpretation of "connector" is "a structure which may be removably joined or linked together with a cooperating structure (i.e., a mating connector)." (Ex. 25 at 17-22).

However, the district court interpreted "connector" to mean "a structure that electrically links the electrode terminal to the high frequency power supply." (Ex. 26 at 2). The district court's interpretation effectively reads "connector" out of the claim. By interpreting one part of the claim, "connector," to mean what was set forth explicitly in another part of the claim already, "electrically coupling the electrode terminal to the electrosurgical power supply," the words "a connector near the proximal end of the shaft" have no meaning. This was clear legal error. Each element contained in a claim is material to defining the scope of the patented invention. *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 117 S.Ct. 1040, 1049 (1997); *see also Texas Instruments Inc. v. U.S. Int'l Trade Comm'n*, 988 F.2d 1165, 1171 (Fed. Cir. 1993) (It is improper to read an express limitation out of a claim.).

Moreover, the district court's construction of "connector" is *contrary* to the way the term is used in '536 specification. *See Ferguson Beauregard v. Mega*

⁹ The accused products are arthroscopic surgical instruments which use high frequency (i.e., RF) energy to cut or coagulate tissue. The instruments must be electrically coupled to an RF electrosurgical power supply to be used.

Sys., LLC, 350 F.3d 1327, 1338-39 (Fed. Cir. 2003). The specification makes clear that a “connector” as used in the patent must be removable. (Ex. 13 at, e.g., col. 10, lines 47-52 and Fig. 2C). Thus, the district court’s construction of “connector” was incorrect and should be overturned. Under Smith & Nephew’s construction, which is supported by the specification, none of the accused products would infringe the ‘536 patent since none have a “connector” which is removable.

This is just one example of the construction issues that Smith & Nephew intends to raise on appeal,¹⁰ and for which Smith & Nephew has at least a reasonable likelihood of success. In all, the parties disputed over 15 separate claim construction terms. (See Ex. 25). This factor also favors a stay.

c. The District Court Allowed the Jury to Decide the Validity of a Certificate of Correction in a Case of First Impression

The parties hotly disputed the validity of a Certificate of Correction in this case that effected substantial changes to the claims. It was undisputed, and the district court held, that without the Certificate there would have been no infringement of U.S. Patent No. 5,697,882 (Ex. 14) by any of the accused products.

¹⁰ There are a number of claim construction issues, each completely dispositive of a particular patent. For example, with respect to the ‘536 patent, Smith & Nephew will likely appeal the district court’s claim construction of the terms “system” and “connector.” If Smith & Nephew were to prevail on either of those issues, that would completely dispose of the ‘536 patent with respect to all accused products, and nullify any injunction. This is particularly significant because the ‘536 patent is the only patent which includes apparatus claims; the other two patents are method patents. Thus, Smith & Nephew would be free to manufacture the accused products for use outside the United States, and could also sell its products in the United States for noninfringing uses. See *Joy Tech., Inc. v. Flakt, Inc.*, 6 F.3d 770, 773-74 (Fed. Cir. 1993). Similar arguments are available for the other two patents-in-suit. (Exs. 14 and 15).

(Ex. 11 at 11, n.6). In what may be a case of first impression, the court allowed the jury to decide the validity of a Certificate of Correction. Certainly, this was contrary to the procedure in the seminal case of *Superior Fireplace v. Majestic Products*, 270 F.3d 1358, 1368 (Fed. Cir. 2001). It was also contrary to the pretrial submissions and arguments of *both* parties, where Smith & Nephew and ArthroCare agreed that this was an issue of law for the Court to decide rather than the jury. (See Ex. 25 at 35-37; Ex. 34 at 157). Thus, as it did in *Markman* when instructing the District Courts that claim construction was a pure question of law for the court and not for juries, Smith & Nephew will ask this Court to use this appeal to define the proper roles of courts and juries.

2. No Real Harm to ArthroCare

ArthroCare will suffer no real harm here since it has chosen to forego exclusivity and, by its own admission, license all other competitors in the market. The presumption of injury to the patentee only arises when a clear showing of patent validity and infringement has been established. *H. H. Robertson v. United States Deck, Inc.*, 820 F.2d 384, 390 (Fed. Cir. 1987), abrogated on other grounds by *Markman v. Westview Instruments, Inc.*, 52 F.3d 967 (Fed. Cir. 1995). However, even if such a presumption does arise, it is rebuttable, particularly in cases where the patentee is willing to accept money compensation instead of exclusivity. *Id.*

The district court relied heavily on a presumption of irreparable harm associated with patents. (Ex. 11 at 12-13). That presumption is clearly rebutted by the fact that ArthroCare has long ago forgone exclusivity by licensing all other

competitors in the market, [

]. See *Polymer Tech., Inc. v. Bridwell*, 103 F.3d 970, 974 (Fed. Cir. 1996) (presumption of irreparable harm rebutted since patentee has “engaged in a pattern of granting licenses under the patent...such that it may be reasonable to expect that invasion of the patent right can be recompensed with a royalty rather than with an injunction”). In the context of a motion to stay, this Court has repeatedly held that the patentee’s willingness to forego exclusivity and license competitors demonstrates that there would be no harm to ArthroCare by staying the injunction. See *E.I. DuPont De Nemours & Co. v. Phillips Petroleum Co.*, 835 F.2d 277, 278 (Fed. Cir. 1987) (no harm to patentee since ‘DuPont ... has never sought to exclude others ... but rather has licensed all willing competitors’); *Standard Havens*, 897 F.2d at 514. This also favors a stay.

3. Harm to Smith & Nephew

If this Court does not stay the injunction and Smith & Nephew prevails on appeal *or* the claims of the patents-in-suit are amended during reexamination, then Smith & Nephew will have been wrongly removed from a market whose barrier to entry is high and its reentry would be highly improbable. Smith & Nephew's ElectroBlade and Saphyre products are the result of more than 27 man years of concerted research and development efforts, manufacturing innovation, clinical assessment and regulatory work. (See Ex. 35, Sparks Decl., ¶ 3). Numerous Smith & Nephew employees derive their livelihood from the manufacture and sale of these products. *Id.* Smith & Nephew spent [

]. *Id.* It is beyond contention that once enjoined, Smith & Nephew will be unable to recover a position in this market. The entirety of Smith & Nephew's investment, all of its employees' contributions, and the capital it has devoted to these products will be lost upon entry of an injunction.

On the other hand, if the stay is granted and Smith & Nephew does not prevail on any issue during appeal *and* none of the claims are amended during reexamination, ArthroCare can be compensated in the form of monetary damages, which it has shown is sufficient by licensing every other competitor in the market. It is evident that the actual harm to Smith & Nephew in denying the stay would be far greater than any possible harm to ArthroCare if the stay is granted.

4. Public Interest

a. **The ElectroBlade And Saphyre Are Uniquely Beneficial Medical Products, And The Public Interest Would Be Harmed By An Injunction**

The public interest would be better served by a stay of any injunction entered in this case. Denying a stay in this case will deprive surgeons of their arthroscopic instruments of choice, which have features offered by no other products. This is a significant detriment to surgeons and the well being of patients.

For example, Smith & Nephew's Saphyre product includes the unique CoolBack feature, which helps prevent inadvertent electrical contact with articular cartilage, thus lowering the risk of irreversible cartilage cell death within the patient's joint during surgery. (Ex. 27, Konsin Dec., ¶ 5-6; Ex. 28, Fanton Dec., ¶ 4). This feature is not available on any alternative products. (*Id.* at ¶ 6). In fact,

several documents reflects so much surgeon dissatisfaction with ArthroCare's products that the Saphyre was described as: "Major Improvement, when can we replace all the ArthroCare?" (Ex. 29 at ORA 0057095). Such comments confirm that the immediate removal of the Saphyre will deprive doctors and patients access to the best medical devices available, contrary to the public interest.

Even more compelling is the lack of any acceptable substitute for Smith & Nephew's ElectroBlade product. The ElectroBlade product uniquely combines an arthroscopic shaver (*i.e.*, a mechanical rotary instrument for resecting tissue) with RF coagulation capabilities, thus allowing surgeons to resect soft tissue, coagulate bleeding tissue and continue resecting, or cut and coagulate simultaneously, all with a single instrument. (Ex. 30, Majors Dec., ¶¶ 4 and 5; *see also* Ex. 31). Prior to the introduction of the ElectroBlade, surgeons had to switch between separate mechanical shavers and RF coagulation devices. (*Id.* at ¶ 4). Combining these two devices into the ElectroBlade eliminated having to switch instruments during surgery, decreasing surgical time and thus decreasing patient morbidity. (*Id.* at ¶ 5). There is no alternative product that provides the same benefits to the surgeon and patient as the ElectroBlade. (*Id.* at ¶ 7). If the ElectroBlade product were taken off the market and no longer available, surgeons would revert to traditional approaches to resect tissue and control bleeding, requiring the use of tourniquets, and increasing surgery time. (Ex. 27, Konsin Dec., ¶ 5). In short, denying a stay in these circumstances would cause direct harm to substantial numbers of patients.

Accordingly, the public interest factor tips quite strongly in favor of staying the injunction pending appeal.

b. A Stay Avoids Rewarding ArthroCare's Anti-Competitive Actions

Staying the injunction pending the resolution of the antitrust claim is particularly appropriate given the unusual circumstances of anticompetitive intent present in this case, as described above. The injunction in this case should be stayed until the antitrust issue is resolved because the injunction and ArthroCare's attempts to acquire an injunction are central issues to the antitrust counterclaim on which Smith & Nephew has yet to be heard, and the public interest is best served by eliminating such anti-competitive behavior. Once ArthroCare's anti-competitive acts can be judicially determined, its claims for injunctive relief can be revisited. Thus, this factor further favors a stay.

C. NO BOND SHOULD BE NECESSARY FOR THIS STAY

Smith & Nephew is a large, financially sound medical device company, which ArthroCare has acknowledged could pay any damages award. (Ex. 33 at 17). Accordingly, no bond should be necessary to support the stay pending appeal.

IV. CONCLUSION

For all of the foregoing reasons, this Court should stay the district court's injunction pending appeal.

Statement Pursuant to Fed. Cir. R. 27(a)(5)

Counsel for Smith & Nephew has discussed the present motion with opposing counsel. ArthroCare says it objects to this motion and will file a response. Ethicon also says that it objects to this motion, but is unsure whether it will file a response.

Respectfully Submitted,



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CERTIFICATE OF SERVICE

I certify that two copies of the foregoing **Non-Confidential Version of Smith & Nephew's Emergency Motion To Stay Injunction Under Federal Circuit Rule 8** was served on this 29th day of April 2004, as follows:

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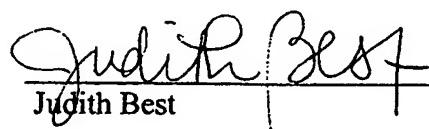
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